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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|--|------------------------------|----------------------|-------------------------|--------------------|--|
| 10/615,342 | 07/07/2003 | David Scott Wishart | 080586-2.00US | 080586-2.00US 8720 | |
| 20350 | 7590 06/17/2004 | | EXAMINER | | |
| TOWNSEND AND TOWNSEND AND CREW, LLP | | | WACHSMAN, HAL D | | |
| TWO EMBARCADERO CENTER EIGHTH FLOOR | | ART UNIT | PAPER NUMBER | | |
| SAN FRANCI | SAN FRANCISCO, CA 94111-3834 | | | 2857 | |
| | | | DATE MAILED: 06/17/2004 | | |

Please find t elow and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|---|---|----------------|--|--|--|--|
| | 10/615,342 | WISHART ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Hal D Wachsman | 2857 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>07 Ju</u> | ıly 2003. | | | | | |
| | action is non-final. | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4) ☐ Claim(s) 65-77 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 65-77 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10)⊠ The drawing(s) filed on <u>07 July 2003</u> is/are: a)□ accepted or b)⊠ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 10/416,988. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08). Paper No(s)/Mail Date 8-14-03, 8-20-03, 12-22-03, 1-20-04 | Paper No(s)/Mail D 5) Notice of Informal F | | | | | |

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1. The drawings are objected to because what is shown in Figure 1 was known in the prior art (see page 7, lines 8-9 of the specification) but has not been labeled as "Prior Art". Appropriate correction is required.

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- 2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see page 12, lines 22-23, of the specification). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.
- 3. There is no statement of continuing data on page 1 of the specification.

 Appropriate correction is required.
- 4. The Abstract is objected to because it is greater than 150 words and contains purported merits (i.e. "..an accurate measurement of pH..). In "NMR" should be defined and the "PA...." after the last line of the Abstract is not appropriate to have in an Abstract and needs to be deleted. Appropriate correction is required.
- 5. The information disclosure statement filed 12-22-03 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. Because of the above, WO 98/39664 which was not in the English language (with the exception of the Abstract) was not considered.
- 6. The listing of references in the specification (see page 12, lines 7-9, of the specification) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the

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Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

- 7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 8. Claims 65-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The body of claim 65 cites "producing a position value for at least one peak of a reference spectrum **as a function** of a measured condition of the test sample, and a property of said at least one peak in a base reference spectrum" however the language "as a function" does not particularly point out how exactly the measured condition of the test sample and a property of the at least one peak in a base reference spectrum are used to produce the position value. This same type of problem also occurs in claim 67, line 2, claim 74, lines 5-7, claim 75, lines 4-6, claim 76, lines 3-5, claim 77, lines 8-10. Claim 65, line 4, cites "a reference spectrum" but a reference spectrum for what exactly is being referred to here ? This same type of problem also occurs in claim 69, line 2, claim 74, line 6, claim 75, lines 4-5, claim 76, line 4. Claim 65, lines 5-6, cite "a base reference spectrum" but a base

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reference spectrum of what exactly is being referred to here? This same type of problem also occurs in claim 74, line 7, claim 75, line 6, claim 76, line 5, claim 77, lines 6-7. The preambles of all the claims that depend from claim 65 cite "The process of ..." however the antecedent basis in claim 65 is "...computer implemented process...". Claim 67, line 2, cites "said sample" however the antecedent basis is "test sample". This same type of problem also occurs in claim 68, line 3. Claim 68, line 3, cites "said condition" however the antecedent basis is "measured condition". Claim 69, line 2, cites "a reference spectrum" however is this the same reference spectrum already cited in claim 65 ? Claim 69, line 2, cites "a position value" however is this the same position value already cited in claim 65? Claim 69, lines 2-3, cite "said record" however the antecedent basis is "pre defined record". Claim 70, line 3, cites "said function" however the antecedent basis is "condition value dependent function". Claim 74 cites "A computer readable medium for providing computer readable instructions for causing a processor circuit to...." However it is not clear how the functionality of the computer readable medium is being realized if the instructions are not being executed. Claim 77, lines 8-9, cite "a derived reference spectrum" but derived from what exactly? Claim 77, line 9, cites "the position" however the antecedent basis is "position value". Claim 77, line 10, cites "a base reference spectrum" however is this the same base reference spectrum previously cited in the claim?

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 76 is rejected under 35 U.S.C. 112, first paragraph, because the claim recites, solely, a single "means" ("processor circuit programmed to...") and therefore the claim is of undue breadth (see MPEP 2164.08(a) and In re Hyatt, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983)).

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 12. Claims 65, 66 and 68-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Otvos (5,343,389).

As per claim 65, Otvos (Abstract, col. 2 lines 40-46, col. 3 lines 65-67, cols .4-5 – Table 1, col. 5 lines 22-32, 35-51, 60-68, col. 6 lines 1, 2, 41-54, col. 7 lines 57-59, col. 9 lines 37-51, col. 13 lines 56-65) discloses "producing a position value for at least one peak of a reference spectrum as a function of a measured condition of the test sample, and a property of said at least one peak in a base reference spectrum".

As per claim 66, Otvos (columns 4-5 – Table 1, col. 3 lines 23-25, col. 6 lines 2-28) discloses the feature of this claim.

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As per claim 68, Otvos (columns 4-5-Table 1, col. 8 lines 32-42) discloses the feature of this claim.

As per claim 69, Otvos (col. 3 lines 23-27, col. 6 lines 14-28, col. 9 lines 49-51, col. 11 lines 26-46, col. 13 lines 66-68, col. 14 lines 1-2, 7-9) discloses the feature of this claim.

As per claim 70, Otvos (col. 3 lines 23-27, col. 6 lines 14-28, col. 8 lines 32-42, col. 9 lines 49-51, col. 11 lines 26-46, col. 13 lines 66-68, col. 14 lines 1-2, 7-9) discloses the feature of this claim.

As per claim 71, Otvos (col. 8 lines 32-42, col. 11 lines 7-12) discloses the feature of this claim.

As per claim 72, Otvos (col. 3 lines 23-27, columns 4-5-Table 1, col. 6 lines 14-28, col. 8 lines 32-42, col. 9 lines 49-51, col. 11 lines 26-46, col. 13 lines 66-68, col. 14 lines 1-2, 7-9) discloses the feature of this claim.

As per claim 73, Otvos (col. 8 lines 32-42, col. 11 lines 7-12) discloses the feature of this claim.

As per claim 74, Otvos (Abstract, figures 6A-6G, figure 7, col. 2 lines 40-46, col. 3 lines 65-67, cols .4-5 – Table 1, col. 5 lines 22-32, 35-51, 60-68, col. 6 lines 1, 2, 41-54, col. 7 lines 57-59, col. 8 lines 3-13, 38-40, col. 9 lines 37-51, col. 13 lines 56-65) discloses "a set of codes for directing the processor circuit to produce a position value.....and a property of said at least one peak in a base reference spectrum".

As per claim 75, Otvos (Abstract, figures 6A-6G, figure 7, col. 2 lines 40-46, col. 3 lines 65-67, cols .4-5 – Table 1, col. 5 lines 22-32, 35-51, 60-68, col. 6 lines 1,

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2, 41-54, col. 7 lines 57-59, col. 8 lines 3-13, 38-40, col. 9 lines 37-51, col. 13 lines 56-65) discloses "a signal segment comprising codes operable to cause the processor circuit to produce a position value... and a property of said at least one peak in a base reference spectrum".

As per claim 76, Otvos (Abstract, figures 6A-6G, figure 7, col. 2 lines 40-46, col. 3 lines 65-67, cols .4-5 – Table 1, col. 5 lines 22-32, 35-51, 60-68, col. 6 lines 1, 2, 41-54, col. 7 lines 57-59, col. 8 lines 3-13, 38-40, col. 9 lines 37-51, col. 13 lines 56-65) discloses "a processor circuit programmed to produce a position value....and a property of said at least one peak in a base reference spectrum".

As per claim 77, Otvos (Abstract, figure 7) discloses "means for receiving a measured condition value representing a condition of the test sample. Otvos (Abstract, col. 2 lines 40-46, col. 3 lines 65-67, cols .4-5 – Table 1, col. 5 lines 22-32, 35-51, 60-68, col. 6 lines 1, 2, 41-54, col. 7 lines 57-59, col. 9 lines 37-51, col. 13 lines 56-65) discloses "means for receiving a representation of a position of at least one peak in a base reference spectrum" and "means for producing a position value for at least one peak…and the position of said at least one peak in a base reference spectrum".

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

⁽a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Otvos (5,343,389) in view of "Checking pH without an Electrode" (Sykes et al.).

As per claim 67, Sykes et al. (pages 479-11 and 479-12) teach the feature of this claim. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the techniques of Sykes et al. to the invention of Otvos as specified above because as taught by Sykes et al. (page 479-11) chemical shifts are pH dependent.

15. The following references are cited as being art of general interest: Otvos et al. (6,617,167) which disclose producing a measured lipid signal lineshape of an NMR spectrum, Raftery et al. (6,696,838) which disclose nuclear magnetic resonance analysis of multiple samples, Tamura et al. (5,707,875) which disclose selective observation of nuclear magnetic resonance signals and Meyer et al. (5,218,529) which disclose the analysis of free induction decays.

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Hal D Wachsman whose telephone number is 571-272-

2225. The examiner can normally be reached on Monday to Friday 7:00 A.M. to 4:30

P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Marc Hoff can be reached on 571-272-2216. The fax phone number for the

organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Primary Examiner

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June 13, 2004